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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,544

10/17/2007

Naoya Kobayashi

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

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DELIVERY MODE

01/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,544	Applicant(s) KOBAYASHI ET AL.	
	Examiner Michael C. Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 6, 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-10 are pending.

Election/Restrictions

It is noted that claim 9 in the preliminary amendment should have been included with Group II and claim 10 in the preliminary amendment should have been included with Group I.

Applicant's election of Group I, claims 1-5 and 7 (and 10), in the reply filed on 10-29-09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6, 8 and 9 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10-29-09.

Claim 1 is drawn to a reversibly immortalized mammalian liver cell line containing an immortalizing gene between a pair of site-specific recombination sequences and a suicide gene in the outside of the pair of site-specific recombination sequences, wherein the suicide gene can exhibit its function after excision of the pair of site-specific recombination sequences.

"Reversibly immortalized" is defined as a cell brought into a condition capable of proliferating immortally by transducing an immortalizing gene into the cell; after proliferation of the cells up to the desired cell number, the cell division is arrested by

excising the immortalizing gene so that the condition of the cell is reverted to the former condition with high safety.

Immortalizing genes encompass SV40T, human telomerase reverse transcriptase (hTERT) and the like (pg 10, lines 6-17). Immortalizing genes include papillomaviruses E6 and E7, adenovirus E1A, PBV, human T-cell leukemia virus, herpes virus saimiri, oncogenes, mutant p53 gene (Katakura, Methods Cell Biol., 1998, Vol. 57, pg 59-91). Site specific recombination sequences such as LoxP and FRT are described on pg 9, line 22 and were known in the art at the time of filing. Suicide gene were known in the art and described in the paragraph bridging pg 10-11.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because “wherein said mammalian is human” is grammatically incorrect. Clarification is required.

Claim 3 is indefinite because it does not clearly set forth the structure of the promoter or clearly indicate from the promoter cannot come.

Claim 4 is indefinite because use of parentheses makes the claim unclear. It cannot be determined if the phrase in parentheses is part of the claim or not.

Claim 5 is indefinite because it cannot be determined how the cell is structurally of functionally different than the cell of claim 1. Accordingly, claim 10 (dependent upon claim 5) is likewise indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Westerman (PNAS, Aug. 1996, Vol. 93, pg 8971-8976), Salmon (Molecular Therapy, Oct. 2000, Vol. 2, No. 4, pg 404-414), Kobayashi (Science, Feb. 18, 2000, Vol. 287, pg 1258-1262), Kobayashi (Human Cell., March 2000, Vol. 13, No. 1, pg 7-13), Kobayashi (Saisei Iryo, Nov. 2002, Vol. 1, No. 2, pg 23-28) and Kobayashi (Cell Technology, June 2000, Vol. 19, No. 6, pg 864-868).

The references all taught a reversibly immortalized human liver cell line containing an immortalizing gene between a pair of site-specific recombination sequences and a suicide gene in the outside of the pair of site-specific recombination sequences, wherein the suicide gene can exhibit its function after excision of the pair of site-specific recombination sequences. See for example Fig. 1 of Westerman which shows a vector encoding SV40T and SHVTK genes with FRT sites used to transfect various cells, such as mammalian liver cells. Claim 3 has been included because the promoters described in the references are not from virus. Claim 4 has been included

Art Unit: 1632

because the structure of the human liver cells described in the references (especially by Kobayashi, an inventor in the instant application) is the same structure as the cells of accession number FERM BP-08657.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner